

### REMARKS

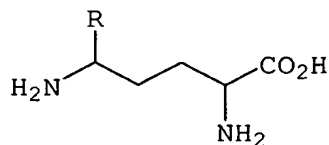
Claims 1, 3, 4, and 6-17 are pending in the application. Claim 3 has been cancelled by this amendment. Therefore, claims 1, 4, and 6-17 are at issue.

Claim 1 has been amended to incorporate the features of originally filed, and now-cancelled, claim 3. Support for this amendment can be found in claim 3 and in the specification at page 13, lines 11-15, for example.

Claims 1, 3, 4, 6-9, 13, 14, 16, and 17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gerhart et al. U.S. Patent No. 4,902,719 ('719). In view of the amendment to claim 1, and for the reasons set forth below, it is submitted that the rejection of claims 1, 4, 6-9, 13, 14, 16, and 17 as being anticipated by, or obvious over, the '719 patent is in error.

In particular, the claims now recite a composition comprising a particularly claimed diamino carboxylic acid, a water-soluble polymer, and a carrier comprising water. The presently claimed composition is neither taught nor suggested by the '719 patent.

The '719 patent is directed to derivatives of ornithine having a formula:



wherein R is  $-\text{CH}_2\text{F}$ ,  $-\text{CHF}_2$ ,  $-\text{CHClF}$ ,  $-\text{C}\equiv\text{CH}$ ,  $-\text{CH}=\text{CH}_2$ , or  $-\text{CH}=\text{C}=\text{CH}_2$ . The structural specificity of the ornithine derivatives disclosed in the '719 patent is impor-

tant because the derivatives are inhibitors of the enzyme L-Ornithine:2-oxoacid aminotransferase (OAT).

Because the present claims do not recite an ornithine derivative disclosed in the '719 patent, the '719 patent cannot anticipate the present claims. It also is submitted that the present claims would not have been obvious over the '719 patent.

A person skilled in the art would have had no motivation to substitute ornithine for an ornithine derivative disclosed in the '719 patent because the derivatives disclosed in the '719 patent are intended to inhibit OAT and thereby avoid metabolism of ornithine. Thus, the '719 patent teaches elevating *in vivo* ornithine concentrations by inhibiting OAT. If ornithine was present in the composition rather than an ornithine derivative of the '719 patent, the OAT enzyme would not be inhibited and the ornithine would be metabolized in the liver (i.e., ornithine concentrations would be reduced). Therefore, the substitution of ornithine for an ornithine derivative of the '719 patent would totally destroy the desired effects the '719 patent is attempting to achieve. Accordingly, a person skilled in the art has no incentive to utilize ornithine in the '719 patent because there would be no possibility of successfully accomplishing the effects desired by the '719 patent.

In addition, the '719 patent is directed to an *in vivo* composition for therapeutic uses. The present claimed compositions are for *in vitro* use in the assay for dialdehydes. There is no nexus between these two disparate uses. Thus, persons in the art of analyte assays would not consider art in the area of

therapeutic compositions to treat deficiencies of ornithine, and vice versa.

In summary, because substitution of ornithine for an ornithine derivative of the '719 patent would destroy the teachings of the '719 patent, and because the subject matter of the '719 patent is in no way related to, and nonanalogous to, the subject matter of the present claims, it is submitted that claims 1, 4, 6-9, 13, 14, 16, and 17 are novel over the '719 patent, and the claims also would not have been obvious to a person skilled in the art over the '719 patent. The rejection of claims 1, 4, 6-9, 13, 14, 16, and 17 over the '719 patent, therefore, should be withdrawn.

Claims 1, 3, 4, 7-12, and 15 stand rejected under 35 U.S.C. §102(b) as being anticipated by Robinson et al. U.S. Patent No. 5,603,923 ('923). The basis of this rejection is that the '923 patent discloses a composition containing lysine, hydroxyethylcellulose, and a carrier. The examiner particularly relies upon Examples VII-IX at column 16 of the '923 patent. For the reasons set forth below, it is submitted that this rejection is in error and should be withdrawn.

The '923 patent cannot anticipate present claims 1, 4, 7-12, and 15 because these claims recite a *water-soluble* polymer. The sole polymer disclosed in the examples at column 16 of the '924 patent is cetyl hydroxyethylcellulose, which, contrary to the examiner's contention, is different from hydroxyethylcellulose and is *not* water soluble. See the attached technical information showing the cetyl hydroxyethylcellulose is a *hydrophobically* modified compound.

Accordingly, the present claims are novel over the '923 patent.

The present claims also would not have been obvious to a person skilled in the art over the '923 patent. The '923 patent is directed to a self-tanning composition containing dihydroxyacetone as the active ingredient. The dihydroxyacetone is stabilized by an amino acid, like lysine. Dihydroxyacetone and an amino acid, plus a sulfite salt or a pH less than 4, are required ingredients in the self-tanning compositions of the '923 patent. The '923 patent also discloses numerous classes of compounds and individual compounds that are used in cosmetic and personal care compositions. The examples relied upon by the examiner contain more than ten ingredients, both essential ingredients and optional ingredients selected from the extensive lists of compounds provided in the '923 patent.

A person skilled in the art of analyte assays first would not look to the '923 patent because the cosmetic and personal care arts are so far removed in subject matter from the art of *in vitro* assays for analytes. Second, even if these two diverse arts are considered analogous, persons skilled in the art would not consider making the modifications to the compositions of the '923 patent that are needed to arrive at a presently claimed composition useful to assay for di-aldehydes. The skilled person then would have to make a jump in logic to conclude that the modified self-tanning composition could be used to assay for di-aldehyde.

In particular, a person skilled in the art would have to delete an essential ingredient from the

'923 patent, i.e., the dihydroxyacetone, which would completely destroy the teachings of the '923 patent (i.e., no self-tanning could occur). Then, a water-soluble polymer would have to be substituted for the water-insoluble polymer, i.e., cetyl hydroxyethylcellulose, of the '923 patent. The '923 patent provides no incentive to make either of these substitutions, let alone both substitutions. The '923 patent contains no teachings or suggestions that link self-tanning to dialdehyde assay, thus there is no motivation for persons skilled in the art of dialdehyde assays to even consider such substitutions.

In summary, the present claims are novel, and are nonobvious over the '923 patent. It appears that the examiner has used hindsight construction to select a few related ingredients from a patent in an unrelated art that discloses a multitude of compounds in order to arrive at the presently claimed compositions. Accordingly, it is submitted that the rejection of claims 1, 4, 7-12, and 15 as being anticipated by the '923 patent under 35 U.S.C. §102(b) should be withdrawn. It also is submitted that these claims would not have been obvious over the '923 patent under 35 U.S.C. §103.

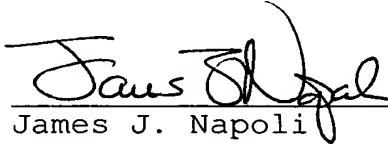
In summary, it is submitted that all pending claims are now in proper form and scope for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Respectfully submitted,

**MARSHALL, GERSTEIN & BORUN LLP**

By

A handwritten signature in dark ink, appearing to read "James J. Napoli", is written over a horizontal line.

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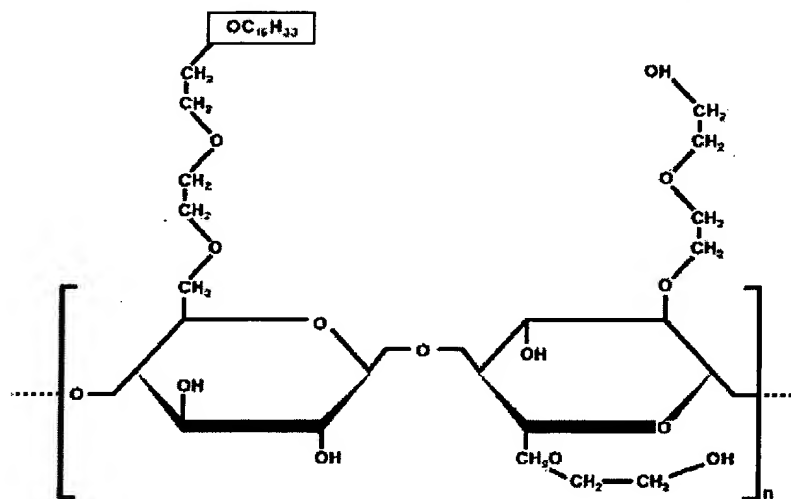
Chicago, Illinois  
May 10, 2004

**Natrosol® Plus CS** hydrophobically modified hydroxyethylcellulose**Characteristics**

- Associative thickener
- Broad pH stability
- Shear thinning
- Suspension of solids
- Coemulsifier
- Surfactant compatible
- Alcohol compatible
- Nontacky skin feel

**Applications**

- Skin care
- Shampoo and conditioner
- Hair styling products
- Wipes
- Liquid soap
- Body wash
- Sun care
- Hand sanitizer



Idealized structure of HMHEC, HE M.S. = 2.5

**Tradename:** Natrosol *Plus* CS hydrophobically modified hydroxyethylcellulose  
**INCI name:** Cetyl hydroxyethylcellulose

**Other names:** HMHEC  
**Charge:** Nonionic

For help in selecting the most appropriate grades for your formulations or applications, please [Contact Us](#).

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